

REMARKS

Claims 1, 5-16, 35, 36 are pending herein. Claim 1 has been amended, Claims 18 and 38 to 41 have been cancelled, and Claims 42 to 47 have been added.

In the Office Action, Claims 1, 5, 9, 10, 12, 13 to 16, 35, and 36 have been rejected as being unpatentable under 35 U.S.C. § 102(b) and 103(a) over the Vykhodtseva et al. article. Claim 18 was indicated as containing allowable subject matter. The Examiner's attention is directed to amended Claim 1, into which the language from Claim 18 has been incorporated. It is believed that the amendment to Claim 1 overcomes the rejections under § 102(b) or 103(a).

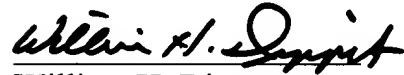
Parent U.S. Patent Application Serial No. 08/939,289 issued as U.S. Patent No. 6,113,858, which is the subject of Reexamination No. 90/006,339. The Examiner's attention is directed to said reexamination, a copy of an Office Action from which is enclosed.

Currently filed herewith is an Information Disclosure Statement, which is believed to include the one uncited reference from the reexamination, but Examiner Shaw should also be consulted in the opinion of Applicants for her opinions and views including her opinions regarding the references.

New Claims 42 to 47 are directed to aspects of Applicants' invention that Applicants believe should be considered herein. Support for said claims can be found, for example, in original Claims 1 to 41.

Reconsideration and allowance of all the claims herein are respectfully requested.

Respectfully submitted,



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MARKED-UP COPY OF CLAIMS

Please amend Claim 1.

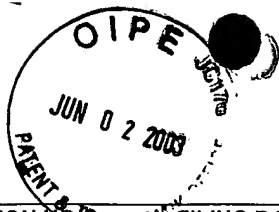
1. (TWICE AMENDED) A method for applying therapeutic ultrasound to a location within a body, comprising activating a transducer to produce ultrasound at a pulse repetition period of $T \leq 1000$ milliseconds and directing this ultrasound in a non-invasive manner to a location within a body and at appropriate power, frequency and pulse duration to generative cavitation at this location;

including the steps of initiating cavitation within the body by applying a first amount of power to the transducer, initiating cavitation at the location within the body, then reducing the power supplied, while maintaining cavitation.

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Patent and Trademark Office

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APPLICATION NO. / PATENT CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
90/006,339	JULY 29, 2002	6,113,558	

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EXAMINER

SHAW, S.

ART UNIT	PAPER
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3737

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DOCKETED

DATE MAILED: JANUARY 31, 2003 *AKZC*
2 Month Office Action
March 31, 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

COPY

cc: Hoffman, Wasson & Gitler,
3rd party attorneys



Office Action in Ex Parte Reexamination

Control No.
90/006,339

Patent Under Reexamination
6113558

Examiner
Shawna J. Shaw

Art Unit
3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

- a ☒ Responsive to the communication(s) filed on 29 July 2002. b ☐ This action is made FINAL.
c ☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 3. <input type="checkbox"/> Interview Summary, PTO-474. |
| 2. <input type="checkbox"/> Information Disclosure Statement, PTO-1449. | 4. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

- 1a. ☒ Claims 1-32 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☒ Claims 2,3,5-21,23,24 and 26-32 are patentable and/or confirmed.
4. ☒ Claims 1, 4, 22 and 25 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ The drawings, filed on 7/29/02 are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a) ☐ approved (7b) ☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the certified copies have

1 ☐ been received.

2 ☐ not been received.

3 ☐ been filed in Application No. _____.

4 ☐ been filed in reexamination Control No. _____.

5 ☐ been received by the International Bureau in PCT application No. _____.

* See the attached detailed Office action for a list of the certified copies not received.

9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.

10. ☐ Other: _____

cc: Requester (if third party requester)

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DETAILED ACTION

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Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Riedlinger of record.

Regarding claim 1, Riedlinger teaches a method for ultrasonic treatment of pathological tissue within a body including: activating a transducer to produce ultrasound at a pulse repetition period (i.e., 1/pulse recurrence rate) of $5 \times 0.1 \text{ ms} = 0.5 \text{ ms}$; and directing ultrasound to a location within the body at appropriate power, frequency and pulse duration to generate controlled cavitation at the location. See col. 2 lines 30-46.

Regarding claim 4, Riedlinger further teaches initiating cavitation and reducing the power to maintain the size of a cavitation bubble (col. 5 lines 37-51 – where the examiner understands power to be directly proportional to the amplitude of the ultrasound pulse).

Regarding claim 22, Riedlinger teaches a method for ultrasonic treatment of pathological tissue within a body including: activating a transducer to produce ultrasound at a pulse repetition period (i.e., 1/pulse recurrence rate) of $5 \times 0.1 \text{ ms} = 0.5$

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ms; and directing ultrasound to a location within the body at appropriate power, frequency and pulse duration to generate controlled cavitation at the location. See col. 2 lines 30-46. Riedlinger further teaches initiating cavitation and reducing the power to maintain the size of a cavitation bubble (see col. 5 lines 37-51 – where the examiner understands power to be directly proportional to the amplitude of the ultrasound pulse).

Regarding claim 25, Riedlinger teaches using a frequency greater than 20kHz (col. 2 lines 43-44).

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Vykhodtesva et al. of record.

Vykhodtesva et al. teach a method for applying therapeutic ultrasound to the brain of a subject including: activating a transducer to produce ultrasound at a pulse repetition period of $1/5 \text{ Hz} = 200 \text{ ms}$; and directing ultrasound to a location within the body (see figure 1) at appropriate power; frequency and pulse duration to produce cavitation at the location (see p. 971 under "Monitoring of cavitation: and p. 971-972 under "Experiment 2").

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

4. The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding: Regarding claims 2 and 3, the prior art does not teach or suggest a method for applying therapeutic ultrasound at a repetition period less than around 1000 ms to generate cavitation at a location of interest using an ultrasound device inserted into the body. Regarding claims 5-21, the prior art does not teach or suggest a method for applying

therapeutic ultrasound with a pulse duration less than around 100 ms to generate cavitation at a location of interest using an ultrasound transmission member at least partially inserted into the body. Regarding claim 23, the prior art does not teach or suggest a method for applying therapeutic ultrasound at a repetition period less than around 1000 ms to generate cavitation at a location of interest using an ultrasound device inserted into the body. Regarding claims 26-32, the prior art does not fairly teach or suggest a method for applying therapeutic ultrasound with a pulse duration less than around 100 ms to generate cavitation at a location of interest using an ultrasound transmission member at least partially inserted into the body.

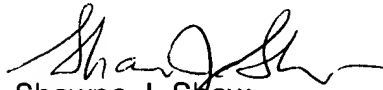
5. In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents **must** be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, which will be strictly enforced.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Shawna J. Shaw", with a long horizontal flourish extending to the right.

Shawna J. Shaw
Primary Examiner
January 23, 2003

**Notice of References Cited**

Application/Control

90/006,339

Applicant(s)/Patent Under
Reexamination
6113558

Examiner

Shawna J. Shaw

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3737

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,209,221	05-1993	Riedlinger	601/2
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
*	U	Vykhodtseva et al. "Histologic Effects of High Intensity Pulsed Ultrasound Exposure with Subharmonic Emission in Rabbit Brain In Vivo," (1995), Ultrasound in Med. & Biol. Vol. 21, No. 7, pp. 969-979
*	V	Ter Harr et al. "Evidence for Acoustic Cavitation In Vivo: Thresholds for Bubble Formation with 0.75 MHz Continuous Wave and Pulsed Beams," (1986) IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. UFFC-33 No. 2 pp. 162-164
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.